

Remarks

Continuity Data

Applicants have amended the specification to add a reference to the International Application for which this application is a National Stage application, and to reference the U.S. Provisional Application from which the International Application claims priority.

Information Disclosure Statement

Applicants respectfully submit that the Examiner is wrong to assert that the Information Disclosure Statement file on March 12, 2001 fails to comply with the provisions of 37 CFR §§1.97, 1.98 and MPEP § 609. According to 35 CFR §1.97 and reiterated in MPEP § 609, sections (a) and (b) state that:

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy *one* of paragraphs (b), (c), or (d) of this section.

(b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

(1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

(3) ***Before the mailing of a first Office action on the merits; or***

(4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114. [Emphasis added].

In the present case, Applicants respectfully submit that the Information Disclosure Statement filed for this application on March 7, 2001 complies with 37 CFR § 1.97(b)(3) -- before the mailing of the first Office action on the merits.

However, nothing in 37 § CFR 1.97 suggests that Applicants must meet the requirements of *both* 1.97 (b)(2) *and* 1.97 (b)(3). In fact, the heading of MPEP § 609(4)(a)I says "Information Disclosure Statement Filed *Before First Action on the*

Merits or Within Three Months of Actual Filing Date (37 CFR 1.97(b)) (emphases added). And 37 CFR 1.97(b) specifically states that “An information disclosure statement shall be considered by the Office if filed by the applicant within any *one* of the following time periods: ...” (*see id.*, emphasis added.)

Applicants further note that the Information Disclosure Statement was filed after the national phase has been entered on February 7, 2001. Indeed, the Information Disclosure Statement included the application serial number on present application, as the USPTO had already assigned the serial number prior to the filing of the IDS (as can be seen on the first page of a copy of the IDS attached herewith, minus the references taken from the File History of the present application and printed from PAIR).

For the reasons stated above, Applicants respectfully submit that the filing date of the IDS for the instant application falls within the time periods set out in CFR § 1.97 (b) (3), so the IDS meets the requirements of CFR § 1.97 (b), and thus meets the requirements of CFR § 1.97 and § 1.98. Applicants therefore request that the IDS, as filed on March 7, 2001, should be considered.

Amendments to the Claims

Applicants have amended claims 18, 21, 23, 50, and 51, and cancelled claims 1-17, 20, 24-49, 53-54, and 57-85. Claims 18, 50 and have been amended to recited that the sequence is the MAIAP SEQ ID NO: 11, for clarity. Claim 21 has been amended to depend only from claim 18, because claim 20 has been cancelled. Claim 51 has been amended to replace the word “method” with “vaccine”, to match the above antecedent basis in claim 50. Claim 50 has also been amended to recite that the vaccine is for “inducing anti-MAIAP antibody in a subject”. Support for this amendment is found in the specification on p. 33, lines 7-19.

Rejections

Claim Objections

1. Claim 20 is cancelled. Claims 18, 21 and 50 have been amended to claim only SEQ ID NO:11, deleting reference to other non-elected inventions and species. Claims 18 and 50 have been amended to specifically recite “the MAIAP SEQ ID NO: 11” for

reasons of clarity. Thus, Claims 21 (which depends from claim 18) and 50 now recite SEQ ID NO: 11 in the context of the MAIAP nucleic acid. Applicants respectfully submit that all claim objections have been addressed and should be removed.

Claim Rejections under 35 USC § 101 – Non-Statutory Subject Matter

Claim 23 has been amended to recited “an isolated cell”. Applicants thus submit that claim 23 is directed to patentable subject matter, and so request withdrawal of the § 101 rejection.

Claim Rejections under 35 USC § 112, para. 2 – Indefiniteness

Claims 20, 59 and 60-62 have been cancelled. Applicants therefore submit that these rejections are moot and should be withdrawn.

Claim Rejections under 35 USC § 112, para. 1 – Written Description and Enablement

Claims 20 and 57-62 have been cancelled. Claims 18 and 50 have been amended to recite that the nucleic acid is specifically the MAIAP nucleic acid SEQ ID NO: 11. Applicants therefore respectfully submit that the pending claims meet the written description requirements and are enabled, and request that the rejections based on written description and enablement be withdrawn.

Rejections under 35 USC § 102(e)


Claims 20-23, 50-52 and 57-62 stand rejected as anticipated by US 6,472,172. However, in light of the amendments to the claims to recite SEQ ID NO: 11, Applicants respectfully submit that US 6,472,172 does not anticipate the presently claimed invention. Withdrawal of the anticipation rejections is therefore requested.

Applicants respectfully submit that all claims are in condition for allowance. Reconsideration of the application and issuance of a notice of allowance are therefore respectfully requested.

Applicants believe that only a one-month extension of time is required; however, in the event that the need for an additional extension under 37 C.F.R. §1.136 has been overlooked, Applicants hereby submit this conditional petition for an additional extension

of time. The applicant believes that \$60 in fees to cover the one-month extension are due at this time; however if additional fees are due for the timely consideration of this application, please charge deposit account number 19-4972. The Examiner is requested to telephone the undersigned if any outstanding issues remain, so that these matters may be resolved expeditiously.

Respectfully submitted,



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ATTORNEY DOCKET NO. 50059/005002

Certificate of Mailing: Date of Deposit: March 7, 2001

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Barry

Printed name of person mailing correspondence

Susan M. Barry
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Glenn Dranoff et al.

Art Unit: Not Yet Assigned

Serial No.: 09/762,577

Examiner: Not Yet Assigned

Filed: February 7, 2001

Customer No.: 21559

Title: Tumor Antigens and Uses Thereof

Assistant Commissioner For Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed. Copies of search reports from a corresponding PCT application are also enclosed.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this Statement an admission that the information is material to patentability.



This statement is being filed within three months of the filing date of the application. If there are any charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

Date: March 7, 2001

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50059.005002 Information Disclosure Statement.wpd



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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

Attorney Docket No.
Serial No.
Applicant
Filing Date
Group
IDS Filed
Customer No.

Sheet 1 of 1
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Glenn Dranoff et al.
February 7, 2001
Not Yet Assigned
March 7, 2001
21559

U.S. PATENTS

Patentee

Class

Subclass

Filing Date
(If Appropriate)

NY CFR § 1.88(b)

Examiner's
Initials

Patent Number

Issue Date

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Country or
Patent Office

Class

Subclass

Translation
(Yes/No)

Examiner's
Initials

Document
Number

Publication
Date

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

Dranoff et al., "Vaccination with irradiated tumor cells engineered to secrete murine granulocyte-macrophage colony-stimulating factor stimulates potent, specific, and long-lasting anti-tumor immunity," *Proc. Natl. Acad. Sci. U.S.A.* 90:3539-3543, 1993.

Dranoff et al., "A phase I study of vaccination with autologous, irradiated melanoma cells engineered to secrete human granulocyte-macrophage colony-stimulating factor," *Human Gene Therapy* 1:111-123, 1997.

Ellen et al., "A case report: Immune responses and clinical course of the first human case of immunotherapy," *Cancer Immunol. Immunother.* 44:10-20, 1997.

Jäger et al., "Strategies for the development of vaccines to treat breast cancer," *Recent Results Cancer Res.* (Germany) 102:94-102, 1998.

Sassan et al., "Characterization of human colon cancer antigens recognized by autologous antibodies," *Int. J. Cancer* 75:652-658, 1998.

Simons et al., "Bioactivity of autologous irradiated renal cell carcinoma vaccines generated by *in vivo* granulocyte-macrophage colony-stimulating factor gene transfer," *Cancer Research* 57:1537-1546, 1997.

Seifert et al., "Vaccination with irradiated autologous melanoma cells engineered to secrete human granulocyte-macrophage colony-stimulating factor generates potent antitumor immunity in patients with metastatic melanoma," *Proc. Natl. Acad. Sci. U.S.A.* 95:13141-13146, 1998.

Takehashi et al., "TGF- β production recognized by human antibody induces human leukocyte antigen A2-restricted cytotoxic T lymphocyte killing of melanoma," *Clin. Cancer Res.* 3:1363-1370, 1997.

Genbank Accession No. A1458805, Hillier et al., "The Human EST Project, March 9, 1999.

Genbank Accession No. A1590782, NCI-CCGAP <http://www.ncbi.nih.gov/ccgap>, National Cancer Institute, Cancer Genome Anatomy Project (CGAP), *Tumor Gene Index*, May 14, 1999.

Genbank Accession No. A1115047, Marra et al., "The WashU-HM Mouse EST Project, September 2, 1998.

EXAMINER

DATE CONSIDERED

EXAMINER: initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of the form with the next communication to applicant.